Academic Sciences

International Journal of Current Pharmaceutical Research

ISSN- 0975-7066 Vol 4, Issue 1, 2012

Research Article

ROLE OF HEALTH CARE PROFESSIONAL IN MANAGING LEAN PHARMACY

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Received: 24 September 2011, Revised and Accepted: 09 November 2011

ABSTRACT

Many excellent reference resources on lean process improvement provide the progressive hospital pharmacy with good background information. Using lean production concepts, an interdisciplinary team implemented a system to standardize delivery locations and improve just –in-time delivery for sterile medication products in an inpatient hospital setting. The primary focus of the team was transforming the current sterile medication preparation process from a 2-to a 5- batch-per-day system. Increasing the frequency of sterile product batches from 2 to 5 batches per day reduced rework and waste by 64%. A true just-in-time process for sterile medication compounding has the potential to be safer and more efficient than traditional batch systems. Additional work is needed to determine if a true just-in-time sterile medication compounding process is feasible in an inpatient hospital setting.

Keywords: Sterile medication, Compounding, Quality improvement, Hospital pharmacy

INTRODUCTION

Lean process improvement is an industry–wide initiative to achieve operational excellence. The lean process approach facilitates improvement of process efficiency and quality while delivery faster service and cost reduction. Compounding and dispensing sterile intravenous products can consume considerable staff resources within a pharmacy. These products also contribute to pharmaceutical expenses. Unfortunately, due to limitations on sterility or stability, these products frequently expire prior to use.The Pharmacy Department at Shri Devraj Urs Medical College and Hospital, a 1200 bedded hospital, reduced waste and rework in the sterile product compounding process by utilizing concepts from lean manufacturing.

In October 2008, the Pharmacy Department began utilizing lean concepts to improve operations. Lean production utilizes concepts of 1-piece flow, a pull system and a culture of continuous improvement to improve process quality and efficiency. The lean identifies seven main types of waste: overproduction, waiting, excess transport, excess processing, excess inventory, excess motion, and defects[1]. Each of these wastes creates excess work and inefficiency within a system. Through elimination if these types of waste, a more reliable and efficient system can be created. Originating with the Toyota Production System (TPS) soon after world war-II, the concepts of lean implementation are no longer confined to manufacturing[1-2]. The lean methodologies have successfully applied to service, administrative process, health care delivery systems including pharmacy operations to improve efficiency and effectiveness[3]. There are basic steps in developing a lean process improvement strategy in any business[4]. Those are assessing the current state, determine the future state workflow, identify the future state original structure, identify priorities and develop the plans[5].

MATERIALS AND METHODS

In February 2009, a team met for a 1-week, rapid improvement event to examine and improve the sterile medication compounding and delivery process. This team was composed of 3 Pharmacists, 2 staff Nurses, 4 Pharmacy Assistants, the coordinating officer, the lab superintendent and administrator from performance improvement. The team focused on reducing several types of waste including over-production, excess inventory, excess transport and motion.

The baseline metrics were defined by the team. The baseline number of compounded doses was established by reviewing sterile compounding records to determine the total number of doses compounded in a 3-day period. The number of doses discontinued after compounding was collected by reviewing the total number of doses that were compounded and discontinued prior to administration. The percentage wasted was determined by dividing doses discontinued prior to administration by the total doses compounded. This work was not designed to assess the value of wasted effort or productive hours in the system.

The turnaround time to the intensive care unit (ICU) was assessed over the same 3-day period. It was collected by measuring the time from when order was scanned to the pharmacy to when the medication was located by the Staff Nurse for every first dose of medication sent from the pharmacy to the ICU during the measurement period. The number of medication storage and delivery locations was measured by counting the areas where medication was stored in the ICU and interviewing ICU staff. After examining the baseline metrics, the team selected aggressive, yet achievable, targets for improvement. The goals of the team were to reduce wasted compounded sterile products by 50%, reduce delivery time for first-dose medications to the ICU by 50% and reduce the number of medication delivery locations in the ICU by 50%.

The team started by mapping the current state of the progress. Prior to the rapid improvement movement, first doses of sterile products were compounded in the pharmacy and delivered via pneumatic tube system to the nursing unit. Once product reached the nursing unit, there was no process for ensuring standard storage of the medication. The staff Nurse would look for the medication in 1 of 6 locations including the tube station, refrigerator, medication in-and out-bins, the patient's room and on the counters of the nursing station. Even, when the product was in the medication in-bin, it could be intermixed with enteral feeding products and other products from central supply. This variability could result in a significant delay for the medication. In addition, because storage was not well controlled, questions about stability, security and safety were identified.

Prior to Lean implementation, repeat doses of compounded sterile products were prepared in 2 batches at 07:00AM and 01:00PM daily. The 07:00AM batch included the doses that were due between 12:00 PM and 11:59PM. The 01:00PM batch included doses that were due between 12:00 AM and 11:59 AM. The team quickly realized that some of the doses on the 1:00 pm batch were prepared up to 18 hours in advance of the administration time.

The team also identified that a significant number of orders were discontinued in the afternoon, just as the products were being prepared. Preparation of product far in advance was classified as "over production" because it resulted in a significant amount of wasted effort in preparing and transporting medications to and from the floor if the order was discontinued prior to administration. While some of the product could be reused, some of it expired before it was returned to the pharmacy and was therefore discarded as waste.

Implemented Changes

To eliminate wasted motion and product, the team implemented several changes on day-3 of the rapid-improvement event. First, the team created a standardized delivery location for all pharmaceutical products. To encourage staff on the nursing unit to use this location, the standard location was positioned next to the pneumatic tube station. ICU staff was educated to put all medication doses that arrived in the pneumatic tube either in the in-bin or to the refrigerator. This change affectively decreased the number of medication storage and delivery locations in the ICU from 5 to 2.

The second change involved implementation of a production process in which the product was prepared closure to the time of actual use. To accomplish a nearly just-in-time production process, production of repeat doses occurred in 5 batches/ day instead of 2. The batch schedule is listed in Table-1.

Finally, the automated dispensing cabinets were rebuilt to accommodate more commonly used pre-made sterile products. By reducing the number of first-dose medications that needed to be labeled and sent from the pharmacy, the team hoped to improve the throughput and delivery time of first-dose medications from the pharmacy.

RESULTS

Follow-up measures were performed at 1-and -6-month intervals after the implementation of the changes. Baseline and follow-up measures appear in Table-2. Compared with baseline, the number of wasted doses of batch-prepared medications was reduced by 64% one month following the improvement event. Through standardization of the delivery locations on the unit, the number of delivery locations available on the unit also decreased from 5 to 2 (a 60% reduction). The delivery time of first-doses to the unit was reduced from 52 to 26 minutes (a 50% reduction).

Table 1: Five-Batch Compounding, delivery and Administration schedule

Compounding Complete	Delivery to Unit complete	Medication Administration Time
07: 30 AM	08: 00 AM	09: 00 AM to 11:59 AM
09: 30 AM	11: 00 AM	12: 00 PM to 03:00 PM
12: 30 PM	02: 00 PM	03: 01 PM to 06:00 PM
03: 30 PM	05: 15 PM	06: 01 PM to 12:00 AM
06: 30 PM	11: 30 PM	12: 01 AM to 08:59 AM

Table 2: Baseline and follow-up Measurements after Implementation of a Lean Production System in a sterile Pharmaceutical Compounding Process

Measurement Period	Total dosesCompounded	Doses discontinuedAfter compounding	% Wasted	Average turnaround time for First Doses
Baseline	507	103	20.3%	52 min
30-day follow-up	575	39	6.8%	26 min
180-day follow-up	361	16	4.4%	25 min

DISCUSSION

The Lean concepts used by this rapid improvement team included creation of standard work, just-in-time delivery and 1-piece flow. A traditional twice daily batch system is the anti-thesis of just-in time delivery and 1-piece flow because medications are produced in mass far in advance of their scheduled administration times[6]. This results in overproduction and excess transport because many medications are discontinued before they are administered. While not evaluated in the study, delivery of medications to the units long before they are due could theoretically result in medication errors because discontinued and un-needed medications are available to Staff Nurses for inadvertent administration. Standardizing delivery locations and increasing batch frequency improved the efficiency and precision of the sterile medication compounding and delivery process. By creating a closure to just-in-time delivery process, a significant amount of waste was removed from the process.

The team faced several challenges when implementing its changes. The team worked with Pharmacy management to modify shift times and duties of some pharmacy assistant shifts. The Pharmacy information system needed to be reconfigured to reflect the new batch times. The exact batch times and staffing times were adjusted by the team over several months following the 1-week improvement event. New bins were procured to separate the central supply and pharmacy delivery areas on the patient care units. An educational campaign was required to ensure pharmacy staff and Staff nurses understood and complied with the new process. In addition, a class 100 Clean room was being constructed during the rapid-improvement event. The disruption of Pharmacy working area caused by the construction added additional difficulty when implementing 5-batch-per-day system.

Initially, many staff members were skeptical of the 5-batch-per-day plan. Intuitively, 5 batches/ day sounded like more work than 2 batches per day. However, once the process stabilized, a number of benefits were evident. First, because waste was reduced, the number of doses made per day was reduced. Completing 5 small batches of 35 doses throughout the day may be less fatiguing than completing 2 large batches of 100 doses each. A batch of 35 sterile products can be completed in under an hour, where as a batch of 100 doses requires approximately 2 hours for completion. The attention to detail to check mathematical calculations and maintain proper sterile technique could be compromised if fatigue occurs during long stretches of continuous compounding.

Several authors have examined the cost effectiveness of various sterile product procurement and preparation techniques[7-10]. It is important for each individual institution to carefully evaluate the cost of its contracted products, the volume and mix of products and the cost of labor, waste and other factors. Pharmacy assistants at this Institution were very interested in purchasing more premade products. However, after a careful analysis that included drug, supply, labor and waste expenses, we determined that purchasing premed or pre-compounded products would increase overall pharmaceutical costs by Rs.72 lakh annually. This expense far exceeded any labor efficiencies that we would expect to gain by utilizing premade medications.

After analysis of overall pharmaceutical purchases and samples of discarded compounded products, it was estimated that the 5-batch-

per-day system reduced pharmaceutical expenditures by Rs. 29 lakh annually. No increase in staff was necessary to achieve these goals. Supply expenditures for implementation totaled less than Rs. 5 thousand. Because a large, cross-functional team was assembled to evaluate this process and implement changes, approximately 500 hours or Rs.7 lakh in labor costs were incurred to design, implement and refine the new process. This initial investment in labor was recouped in product savings within 4 months.

Overall, application of Lean concepts to the sterile product compounding process in Pharmacy reduced wasted motion, transport and product and improved the overall efficiency of the compounding process. With the advent of USP <797>, the process of sterile product compounding has become increasingly complex[11]. Many organizations have redesigned their facilities to ensure the most appropriate environment for sterile compounding. Other organizations have moved towards purchasing more pre-made out-sourced sterile medications.

As the ability to utilize technology to track, deliver and communicate about medications in real-time increases, organizations should challenge themselves to provide just-in-time delivery systems to minimize the potential for waste, rework and error. A just-in-time compounding and delivery process for sterile products could be safer than traditional batch systems because there would be fewer medication doses on the unit that could be administered in error. There would also be limited need for refrigeration or special compounding precautions because every medication would be administered within a few hours of preparation.

CONCLUSION

Fundamentally, the right process produce the right results- whether in health delivery system pharmacies or in manufacturing. For care professional or providers, the right results are providing safe patient doses at the right time and in most efficient manner possible. Increasing the frequency of sterile product batches from 2 to 5 batches per day reduced rework and waste by 64%. A true just-in-time process for sterile medication compounding has the potential to be safer and more efficient than traditional batch systems. Additional work is needed to determine if a true just-in-time sterile medication compounding process is feasible in an in-patient hospital setting.

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